

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

August 3, 2015

SIMILARITY CLINIC MEMORANDUM:

Subject: EPA File Symbol: 2724-IUE
Product Name: RF2236 CDSO-N for dogs
DP Barcode 428371
Decision #: 506636
PC Codes: 128965 (Etofenprox)
067501 (Piperonyl butoxide)
057001 (n-Octyl Bicycloheptene Dicarboximide)
129032 (Pyriproxyfen)

From: Byron T. Backus, Ph.D., Toxicologist
CITAB
Registration Division (7505P)

To: Jennifer Urbanski, PM 04
IVB3
Registration Division (7505P)

Applicant: Wellmark International
1501 E. Woodfield Road
Suite 200 West
Schaumburg, IL 60173

FORMULATION FROM EPA File Symbol 2724-IUE LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Etofenprox	55.0%
*Piperonyl Butoxide (PBO).....	10.0%
**n-octyl bicycloheptene dicarboximide (MGK 264)	1.0%
Pyriproxyfen (Nylar)	0.5%
<u>Other Ingredient(s):</u>	<u>33.5%</u>
Total	100.0%

*(butylcarbityl)(6-propylpiperonyl) ether and related compounds

**MGK® 264, Insecticide Synergist

NYLAR, MGK[®] - Registered Trademarks of McGlaughlin Gormley King Company

BACKGROUND: The registrant is claiming similarity of EPA File Symbol 2724-IUE to EPA Reg. No. 2596-168, and is also selectively citing acute toxicity and companion animal safety studies to support the registration. The MRIDs of the acute toxicity studies are as follows: 48405802 (OCSPP 870.1100), 48405803 (870.1200), 48405805 (870.2400), 48405804 (870.2500), and 48405801 (870.2600). No inhalation study (870.1300) has been cited, but given the nature of this product (spot-on) it is not required and it was not required for the registration of 2596-168.

The five cited acute toxicity studies were previously reviewed by TRB (memorandum for 2596-RAT, dated August 9, 2011) and classified as acceptable. The studies (conducted at Eurofins/PSL) were used to support the registrations of 2596-167, -168 and -169. The test material contained 55% Etofenprox, 10% Piperonyl butoxide, 1% N-octyl bicycloheptene dicarboximide, 1% NyLar (Pyriproxyfen), and 2.3% S-methoprene.

In addition, the registrant is citing the companion animal safety studies in MRIDs 48405807 (conducted on adult dogs) and 48405810 (conducted on 12-week-old puppies). These studies are classified as acceptable and were used to support the registrations of 2596-167, -168 and -169. In addition, the study in MRID 48405810 has been used to support the following dosages and associated weight ranges (refer, for example, to the TRB memorandum dated June 11, 2014 for EPA Reg. No. 2596-168): 0.91 mL (0.031 fl. oz.): 5-14 lbs; 1.95 mL (0.066 fl. oz.): 15-30 lbs; 3.90 mL (0.031 fl. oz.): 31-60 lbs; 6.50 mL (0.220 fl. oz.): 61-150 lbs.

COMMENTS AND RECOMMENDATIONS:

1. After an examination of the CSF for 2724-IUE and a comparison with information in PRISM for 2596-168, CITAB concludes that the two formulations are toxicologically similar.
2. The cited acute toxicity studies and companion animal safety studies are acceptable to support the registration of 2724-IUE
3. Based on the cited acute toxicity studies, the acute toxicity profile for EPA File Symbol 2724-IUE is the following:

Acute Oral	IV	Cited MRID 48405802/Acceptable EPA Reg. No. 2596-168
Acute Dermal	IV	Cited MRID 48405803/Acceptable EPA Reg. No. 2596-168
Acute Inhalation	IV	Waived (as for EPA Reg. No. 2596-168)
Primary Eye	III	Cited MRID 48405805/Acceptable EPA Reg. No. 2596-168
Primary Dermal	III	Cited MRID 48405804/Acceptable EPA Reg. No. 2596-168
Skin sensitization	No	Cited MRID 48405801/Acceptable EPA Reg. No. 2596-168

4. The proposed dosages and weight ranges for 2724-IUE (0.91 mL or 0.031 fl. oz. for 5 to 14 lbs; 1.95 mL or 0.066 fl. oz. for 15 to 30 lbs; 3.90 mL or 0.132 fl. oz. for 31 to 60 lbs; 6.50 mL or 0.220 fl. oz. for 61 to 150 lbs) are consistent with those of EPA Reg. No. 2596-168 and are supported by MRID 48405810.
5. The acute toxicity and the companion animal safety study requirements have been satisfied for 2724-IUE.

LABELING:**PRODUCT ID #:** 002724-00842**PRODUCT NAME:** RF2236 CDSO-N FOR DOGS**PRECAUTIONARY STATEMENTS****SIGNAL WORD:** CAUTION**Hazards to Humans and Domestic Animals:**

Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

First Aid:

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.